



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10146, CMS-10062, CMS-10242 and CMS-685]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes

agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage; *Use:* The purpose of this notice is to provide information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process.

CMS requests approval of changes to a currently approved collection under section 1860D-4(g)(1) of the Social Security Act which requires Part D plan sponsors that deny prescription drug coverage to provide a written notice of the denial to the enrollee. The written notice must include a statement, in understandable language, of the reasons for the denial and a description of the appeals process.

Medicare beneficiaries who are enrolled in a Part D plan will be informed of adverse

decisions related to their prescription drug coverage and their right to appeal these decisions. The notice provides all ways that the beneficiary can file an appeal under one section. The Part D instructions have also been revised to include a paragraph informing providers that in the case that a request for a coverage determination is denied under Part B due to step therapy requirements, a different notice should be given.

This denial notice is primarily issued to Part D plan enrollees (Medicare beneficiaries) and is most commonly sent to enrollees by mail. Relying on electronic transmission of this notice to beneficiaries is impractical. Plans are required by regulation to maintain a website by which beneficiaries can request an appeal. In this version of the notice, website information is more prominently displayed. *Form Number:* CMS-10146 (OMB control number: 0938-0976); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 525; *Total Annual Responses:* 2,887,866; *Total Annual Hours:* 721,967. (For policy questions regarding this collection contact Sara Klotz at (410) 786-1984.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Collection of Diagnostic Data in the Abbreviated RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments; *Use:* The 1997 BBA and later legislation required CMS to adjust per-beneficiary payments with a risk adjustment methodology using diagnoses to measure relative risk due to health status instead of just demographic characteristics such as age, sex, and Medicaid eligibility. The purpose of risk adjustment is to pay plan sponsors accurately based on the health status and diagnoses of their Medicare enrollees. Risk adjustment using diagnoses provides more

accurate payments for Medicare Advantage Organizations (MAO), with higher payments for enrollees at risk for being sicker, and lower payments for enrollees predicted to be healthier.

The BBA constituted the first legislative mandate for health status risk adjustment. Section 1853 (a)(3) of the Social Security Act as enacted by Section 4001 of Subtitle A of the BBA required the Secretary to implement a risk adjustment methodology that accounted for variations in per capita costs based on health status and other demographic factors for payment to Medicare+Choice (now MA) organizations. The new methodology was to be effective no later than January 1, 2000. The BBA also required that M+C organizations submit data for use in developing risk adjusted payments.

Risk adjustment allows CMS to pay plans for the health risk of the beneficiaries they enroll, instead of paying an identical average amount for each enrollee Medicare beneficiaries. By risk adjusting plan payments, CMS is able to make appropriate and accurate payments for enrollees with differences in expected costs. Risk adjustment is used to adjust bidding and payment based on the health status and demographic characteristics of an enrollee. Risk scores measure individual beneficiaries' relative risk and the risk scores are used to adjust payments for each beneficiary's expected expenditures. By risk adjusting plan bids, CMS is able to also use standardized bids as base payments to plans.

CMS' fundamental goal for the abbreviated format RAPS data is to require collection of the minimum data necessary for accurate risk-adjusted payment. We believe that diagnostic data provide the most reliable approach to measuring health status, as required by statute. In the absence of these data, we would not be able to accurately determine the beneficiary's health

(risk) status. *Form Number:* CMS-10062 (OMB control number: 0938-0878); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 761; *Total Annual Responses:* 46,610,448; *Total Annual Hours:* 33,484. (For policy questions regarding this collection contact Michael P Massimini at 410-786-1566.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Emergency and Non-Emergency Ambulance Transports and Beneficiary Signature Requirements; *Use:* The statutory authority requiring a beneficiary's signature on a claim submitted by a provider is located in section 1835(a) and in 1814(a) of the Social Security Act (the Act), for Part B and Part A services, respectively. The authority requiring a beneficiary's signature for supplier claims is implicit in sections 1842(b) (3) (B) (ii) and in 1848(g) (4) of the Act. Federal regulations at 42 CFR 424.32(a) (3) state that all claims must be signed by the beneficiary or on behalf of the Beneficiary (in accordance with 424.36). Section 424.36(a) states that the beneficiary's signature is required on a claim unless the beneficiary has died or the provisions of 424.36(b), (c), or (d) apply. For emergency and nonemergency ambulance transport services, where the beneficiary is physically or mentally incapable of signing the claim (and the beneficiary's authorized representative is unavailable or unwilling to sign the claim), that it is impractical and infeasible to require an ambulance provider or supplier to later locate the beneficiary or the person authorized to sign on behalf of the beneficiary, before submitting the claim to Medicare for payment. Therefore, an exception was created to the beneficiary signature requirement with respect to emergency and nonemergency ambulance transport services, where the beneficiary is physically or mentally incapable of

signing the claim, and if certain documentation requirements are met. Thus, we added subsection (6) to paragraph (b) of 42 CFR 424.36. The information required in this ICR is needed to help ensure that services were in fact rendered and were rendered as billed. *Form Number:* CMS-10242(OMB control number: 0938-1049); *Frequency:* Yearly; *Affected Public:* Private Sector; Business or other for-profits, Not-for-profit Institutions; *Number of Respondents:* 10,229; *Total Annual Responses:* 13,318,440; *Total Annual Hours:* 1,110,757. (For policy questions regarding this collection contact Martha Kuespert at (410) 786-4605.)

4. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease (ESRD) Network Semi-Annual Cost Report Forms and Supporting Regulations; *Use:* Section 1881(c) of the Social Security Act establishes End Stage Renal Disease (ESRD) Network contracts. The regulations found at 42 CFR 405.2110 and 405.2112 designated 18 ESRD Networks which are funded by renewable contracts. These contracts are on 3-year cycles. To better administer the program, CMS is requiring contractors to submit semi-annual cost reports. The purpose of the cost reports is to enable the ESRD Networks to report costs in a standardized manner. This will allow CMS to review, compare and project ESRD Network costs during the life of the contract. *Form Number:* CMS-685 (OMB Control Number: 0938-0657); *Frequency:* Reporting - Semi-annually; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 18; *Total Annual Responses:* 36; *Total Annual Hours:* 108. (For policy questions regarding this collection contact Benjamin Bernstein at 410-786-6570).

Dated: February 26, 2020.

William N. Parham, III,
Director, Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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